UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

JOHN J. TEIXERIA,

Plaintiff,

v.

ST. JUDE MEDICAL, INC.,
ST. JUDE MEDICAL S.C., INC., and
PACESETTER, INC. d/b/a St. Jude Medical Cardiac Rhythm Management Division,

Defendants.

REPORT AND RECOMMENDATION

14-CV-789A

I. INTRODUCTION

The Hon. Richard J. Arcara referred this case to this Court under 28 U.S.C. § 636. (Dkt. No. 6.) Pending before the Court are two motions by defendants St. Jude Medical, Inc., St. Jude Medical S.C., Inc., and Pacesetter, Inc. ("St. Jude" collectively). St. Jude has moved (Dkt. Nos. 4, 16) to dismiss the amended complaint of plaintiff John Teixeira ("Teixeria") under Rule 12(b)(6) of the Federal Rules of Civil Procedure ("FRCP"). St. Jude argues that Teixeira's claims regarding his implantable defibrillator and heart lead are preempted by regulations administered by the U.S. Food and Drug Administration ("FDA"). To the extent that any of Teixeira's claims would survive preemption, they would fail to establish enough of a connection between any alleged regulatory violations by

St. Jude and the injuries that Teixeira suffered. Teixeira opposes this motion by arguing that he has demonstrated how the regulatory violations led to a defective device and by arguing that his state-law claims are only parallel to any federal regulations in question.

Additionally, St. Jude has filed a motion (Dkt. No. 18) to strike a number of paragraphs from the amended complaint, under Rules 11(b)(3) and 12(f). St. Jude originally included with this motion a request to impose sanctions on Teixeira and his counsel for making factual contentions that St. Jude considered baseless. In its reply papers (Dkt. No. 24), St. Jude withdrew the request for sanctions but still asked to strike portions of the amended complaint that allegedly copied complaints from other cases that rejected those same allegations as unsubstantiated. Teixeira opposes this motion by denying that he copied any language from any other complaint and by asserting that the allegations in the amended complaint reflect original research about the history of the defibrillator and heart lead in question.

The Court has deemed the motions submitted on papers under FRCP 78(b). For the reasons below, the Court respectfully recommends granting the motion to dismiss in part and denying the motion to strike in its entirety.[1]

[1] Motions to strike material that does not directly foreclose any claims or defenses generally are non-dispositive, but the reasons to strike here parallel the reasons to dismiss. Out of caution, the Court will use the Report and Recommendation format to address both motions. *Cf., e.g., Zhao v. Kaleida Health*, No. 04-CV-467, 2008 WL 346205, at *1 n.1 (W.D.N.Y. Feb. 7, 2008).

II. BACKGROUND

This diversity case concerns an implantable cardiac defibrillator whose heart wire, or lead, had to be replaced just 14 days after implantation. On September 6, 2011, doctors implanted in Teixeira a defibrillator equipped with a particular lead called the Durata, Model No. 7121Q/65. On September 20, 2011, doctors operated on Teixeira again to replace the lead. The record contains no allegations or other information about where the replaced lead is and whether anyone has examined it.

St. Jude designed and manufactured the Durata lead and has a history of making products like it. Briefly, heart leads of any kind run from a defibrillator planted in the chest wall into the heart itself. The lead sends information to the defibrillator about irregular heart rhythms. The defibrillator, when needed, delivers electrical shocks to the heart through the lead. Among other features, the wires making up the lead are coated with insulation to prevent bodily fluids from short-circuiting the defibrillator or otherwise disrupting communication between the lead and the defibrillator. In 2002, St. Jude received FDA approval to market a predecessor to the Durata lead called the Riata lead. Over the next few years, St. Jude received FDA approval for modifications to the Riata design that led to new models and a new line of models called Riata ST. St. Jude later developed a new material, trademarked Optim, to use as insulation for leads within the Riata ST family. According to FDA databases, St. Jude initially called

leads with the new material the Riata STS Optim leads. On January 10, 2008, the FDA approved a change in the trade name for this newest lead, from Riata STS Optim to Durata.

Medical devices such as the Durata lead are subject to significant oversight from the FDA, by way of the Medical Device Amendments of 1976 ("MDA"), Pub. L. 94-295, 90 Stat. 539 (1976) (codified as amended at 21 U.S.C. §§ 351–360fff-7). The MDA creates three classes of medical devices. 21 U.S.C. § 360c. The FDA has classified the Durata lead as a Class III device, which means, *inter alia*, that it "is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C). "Premarket approval is a rigorous process. A manufacturer must submit what is typically a multivolume application. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling. Before deciding whether to approve the application, the agency may refer it to a panel of outside experts and may request additional data from the

manufacturer." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-18 (2008) (internal quotation marks and citations omitted). "FDA further assures the safety and effectiveness of medical devices by regulating their manufacture. To make sure that drugs and medical devices are manufactured to the same high standards that are required for their approval, FDA has developed a set of regulations called the current Good Manufacturing Practices (GMPs). The ultimate purposes of the GMPs is enforcement of quality standards. The GMPs contain systems-oriented requirements for quality control and compliance, which serve the FDA's enforcement purposes and give operational 'guidance' to FDA-regulated firms. They govern personnel and organization, facilities and sanitation, equipment, component control, production and process controls, control of packaging and labeling materials, distribution and installation of devices, and records." Charles S. Zimmerman, 1 Pharm. & Med. Device Litig. § 1:20 (Westlaw 2015).

According to Teixeira's amended complaint, filed on October 15, 2014, St. Jude's Riata leads ran afoul of FDA oversight in ways that raise questions about their Durata leads. In 2012, the FDA inspected one of St. Jude's manufacturing facilities and issued warnings about noncompliance with GMPs that mentioned the Durata lead by name. (*See* Dkt. No. 8 at 5.) The warnings prompted media coverage in late 2012 that raised questions about the Durata lead and about the Optim insulation. The FDA followed up its warnings with a formal warning letter to St. Jude in early 2013. In the warning letter, the FDA accused St. Jude of

producing adulterated devices by way of manufacturing violations pertaining to product testing, verifying device design, maintaining design history files, implementing corrective and preventive actions, and misbranding the Durata lead. (*See id.* at 5–10.) This warning letter came a little over a year after the FDA initiated a recall, on November 28, 2011, of Riata and Riata ST leads. The recall occurred out of concern that insulation on the Riata and Riata ST leads would fail and expose the underlying wiring. From here, Teixeira asserts upon information and belief several factors that led to defective Durata leads. These factors include: lack of consistent insulation diameters as required by federal regulations; lack of consistency in the application, preparation, and manufacturing of wire insulation; failure to follow approved processes for curing and sterilization of insulation; failure to crimp the leads as required by federal regulations; inadequate product inspections and calibrations; and inadequate training of personnel. (*See generally id.* at 19–26.) Teixeira includes in his amended complaint a particular theory of how St. Jude's alleged manufacturing defects and regulatory violations manifested themselves in a lead that had to be replaced after 14 days:

> A natural process of abrasion occurs *in situ* with the insulation surrounding the lead wires or electrical conductors. It is foreseeable that such abrasion will occur with the insulation surrounding the lead wires and the bad wires after implantation. As a result, the lead wires protrude through the insulation, causing them to be in contact with materials and fluids that can prevent the proper functioning of the ICD [the defibrillator]. This protrusion is called "externalization."

> The breach of insulation and externalization of the lead wires on the Riata and Durata Leads can cause the leads to short, and to transmit incorrect information or noise to the pacemaker/defibrillator thereby causing it to produce unnecessary and very painful shocks of electricity, or alternatively, to fail to communicate with the pacemaker/defibrillator at which point the life-saving therapies of the device are unavailable.

(*Id.* at 21 ¶¶ 72–73.)

Teixeira's amended complaint contains six formal claims for relief. In the first claim, Teixeira accuses St. Jude of violating numerous particular regulations and thereby incurring strict liability for a manufacturing defect. In the second claim, Teixeira accuses St. Jude of negligence in manufacturing by violating its duty to manufacture the Durata lead in conformance with federal regulations. In the third and fourth claims, Teixeira asserts negligence and strict-liability theories of a failure to warn, alleging that St. Jude failed to warn him and his doctors that his lead was associated with adverse events and was unsuitable for use. In the fifth claim, Teixeira accuses St. Jude of negligent representation by failing to provide him, his doctors, and the FDA with accurate information about the reliability and safety of the Durata lead. Finally, in the sixth claim, Teixeira accuses St. Jude of breaching express and implied warranties by disseminating information that the Durata lead was safe for foreseeable and intended uses for which it was designed, manufactured, and assembled. The sixth claim includes assertions that representatives of St. Jude made personal representations to

Teixeira and/or his doctors that the Durata lead was safe and long-lasting, that it would not prematurely erode, and that it would not require a surgical intervention.

St. Jude seeks dismissal of the amended complaint for two reasons. First, St. Jude asserts that Teixeira's claims are expressly and implicitly preempted. Specifically, St. Jude argues that the FDA already has approved its design, manufacturing, and labeling processes. According to St. Jude, most of Teixeira's allegations come too close to questioning those processes in themselves, which means that they improperly would add requirements beyond those in the federal regulations. To the extent that any of Teixeira's claims or allegations survive preemption, St. Jude argues that they do not connect any alleged regulatory violations to his injuries. In an effort to avoid preemption, Teixeira attempts to link his allegations of design and manufacturing defects to specific federal regulations. Citing the regulations, though, requires Teixeira to bridge the gap between administrative violations in themselves and actual harm to patients like himself. St. Jude argues that Teixeira has failed to bridge that gap and has only cribbed language from other complaints that does not address his situation. Teixeira opposes the motion by citing the specific manufacturing problems that he stated in his amended complaint and noting how those manufacturing problems each violated federal regulations. Teixeira also notes his theory of how the alleged manufacturing defects translated into a particular form of product failure that caused his injuries. Because Teixeira has linked his allegations of

manufacturing defects to specific federal regulations, he asserts that he is not adding to those regulations and thus does not face preemption.

St. Jude also seeks to strike a number of paragraphs and allegations from the amended complaint. Principally, St. Jude argues that the allegations about federal regulations requiring certain manufacturing specifications are plainly false and copied from another case, *Pinsonneault v. St. Jude Med., Inc.*, No. 12-CV-1717 PJS/JSM, from the District of Minnesota. St. Jude asserts that *Pinsonneault* is the case "where the false allegations originated and were thereafter adjudicated as having no merit." (Dkt. No. 24 at 8.) St. Jude also insists that Teixeira is confusing the Riata and Durata leads. St. Jude concludes that striking the allegations is necessary to protect it from having to defend itself repeatedly against copied allegations that are fabricated. Teixeira opposes this motion by denying any knowledge of *Pinsonneault* when he filed the amended complaint and by denying that he copied any language from any other case. Teixeira then asserts that the Durata lead derived from the Riata lead and is not a completely new device. Finally, Teixeira argues that he has conducted significant original research showing that the FDA, media outlets, and medical professionals all have raised questions about both the Durata and Riata leads, meaning that allegations about each product necessarily will have some features in common.

III. DISCUSSION—MOTION TO DISMISS

A. *Motions to Dismiss Generally*

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks and citations omitted). Court assess Rule 12(b)(6) motions "accepting all factual allegations in the complaint as true, and drawing all reasonable inferences in the plaintiff's favor." *Peter F. Gaito Architecture, LLC v. Simone Dev. Corp.*, 602 F.3d 57, 61 (2d Cir. 2010) (internal quotation marks and citation omitted). "On a motion to dismiss, the court may consider any written instrument attached to the complaint as an exhibit or any statements or documents incorporated in it by reference." *Yak v. Bank Brussels Lambert*, 252 F.3d 127, 130 (2d Cir. 2001) (editorial and internal quotation marks and citation omitted). "Simply stated, the question under Rule 12(b)(6) is whether the facts supporting the claims, if established, create legally cognizable theories of

recovery." *Cole-Hoover v. Shinseki*, No. 10-CV-669, 2011 WL 1793256, at *3 (W.D.N.Y. May 9, 2011) (Arcara, *J.*) (internal quotation marks and citation omitted).

B. *General Principles of Medical Device Preemption*

With exceptions not relevant here, "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). "In [*Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)], five Justices concluded that common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device. We adhere to that view. In interpreting two other statutes we have likewise held that a provision pre-empting state 'requirements' pre-empted common-law duties." *Riegel*, 552 U.S. at 323–24 (alteration in the original) (citations omitted). That said, "State requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA

regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330 (citations omitted).

"Since *Riegel*, courts have found that to plead a parallel state law claim, the plaintiff must allege that the defendant violated a particular federal specification referring to the device at issue. However, a plaintiff may not sue simply because the conduct violates federal law, since there is no private right of action. In other words, section 360k protects a medical device manufacturer from liability to the extent that it has complied with federal law, but it does not extend protection from liability where the state tort claim is based on a violation of federal law." *Rosen v. St. Jude Med., Inc.*, No. 1:13-CV-1159 LEK/CFH, 2014 WL 4257863, at *5 (N.D.N.Y. Aug. 28, 2014) (editorial and internal quotation marks and citations omitted).

Preemption also may occur implicitly. "Congress' intent to preempt state law in a given field may be stated expressly in a statute, or may be expressed implicitly by the enactment of a scheme of federal regulation so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it. Implied preemption also occurs when compliance with both federal and state regulations is an impossibility." *Lamontagne v. E.I. Du Pont de Nemours & Co.*, 834 F. Supp. 576, 580–81 (D. Conn. 1993) (internal quotation marks and citations omitted).

C. *Strict Liability for a Manufacturing Defect*

Having covered the general principles for dismissal and preemption, the Court now turns to Teixeira's first claim for strict liability for a manufacturing defect. A review of New York law will help determine both plausibility and overlap with federal regulatory requirements. "Manufacturers of defective products may be held strictly liable for injury caused by their products—meaning that they may be liable regardless of privity, foreseeability or reasonable care. A product may be defective because of a mistake in the manufacturing process, because of defective design or because of inadequate warnings regarding use of the product." *Sprung v. MTR Ravensburg Inc.*, 788 N.E.2d 620, 622 (N.Y. 2003) (citations omitted). Plaintiffs in New York must fulfill three criteria to establish strict liability against a manufacturer: "(1) that at the time of the occurrence the product is being used (whether by the person injured of damaged or by a third person) for the purpose and in the manner normally intended, (2) that if the person injured or damaged is himself the user of the product he would not by the exercise of reasonable care have both discovered the defect and perceived its danger, and (3) that by the exercise of reasonable care the person injured or damaged would not otherwise have averted his injury or damages." *Codling v. Paglia*, 298 N.E.2d 622, 628–29 (N.Y. 1973).

Here, several factors weigh against dismissal. With respect to plausibility, the parties do not appear to dispute that Teixeira had a defibrillator with the

Durata lead installed on September 6, 2011. The parties also do not appear to dispute that Teixeira had his Durata lead replaced on September 20, 2011. Subject to discovery, Teixeira has formed a preliminary theory as to how a heart lead fails in just 14 days. Teixeira has asserted that federal regulations required certain manufacturing standards and processes, that St. Jude violated those regulations, and that the violations in themselves led to a substandard product. St. Jude objects strenuously to the allegations of federal regulations that have not yet been specified, and the Court will discuss that issue more below. Also, St. Jude almost certainly has its own theories about what happened that have nothing to do with manufacturing, but alternative theories do not detract from the idea that problems with uncontrolled manufacturing plausibly could happen. "The choice between two plausible inferences that may be drawn from factual allegations is not a choice to be made by the court on a Rule 12(b)(6) motion . . . . A court ruling on such a motion may not properly dismiss a complaint that states a plausible version of the events merely because the court finds a different version more plausible." *Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 185 (2d Cir. 2012) (citation omitted).

Teixeira's claim also survives express and implied preemption because his theory of liability stemming from federal regulatory violations does not add to St. Jude's responsibilities. New York's standard for strict liability in itself removes privity, foreseeability, and reasonable care from consideration, thus eliminating

three common sources of additional duties and requirements that would deviate from federal requirements. The extensive PMA process would have supplied the intended purpose and manner for the defibrillator. *Cf. McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 109 (D. Conn. 2014) ("[Plaintiff] alleges a products liability claim predicated on a manufacturing defect, asserting only that the [product] was manufactured *contrary to its federally approved design specifications*, thereby making it unreasonably dangerous."). Teixeira has been careful in his amended complaint not to stray from federal standards when alleging, as noted above, that St. Jude did not monitor its FDA-required manufacturing process and that St. Jude subsequently violated federal regulations by using a substandard process. St. Jude might raise affirmative defenses questioning Teixeira's health and how he cared for his defibrillator, but any debate about Teixeira's duty to mitigate puts responsibility on Teixeira and not St. Jude.

Under these circumstances, Teixeira has set up his claim for strict liability as a parallel requirement that survives scrutiny under Rule 12(b)(6). *See also* 21 C.F.R. § 808.1(d)(6)(ii) ("Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices."). The Court thus recommends denying St. Jude's motion with respect to the first claim.

D. *Negligence in Manufacturing*

Teixeira's second claim requires a minor adjustment compared to his first claim. "A manufacturer is liable in negligence for injury caused by a defective product if it failed to exercise due care in the production of such product. However, the 'decisive issue' in a manufacturing defect case is the existence of the defect without regard to the care exercised by the manufacturer." *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 86 (S.D.N.Y. 2001) (internal quotation marks and citations omitted). As with the strict liability claim, Teixeira has alleged that St. Jude had to follow federal standards when manufacturing its leads, that the FDA flagged St. Jude for falling short of those standards, and that St. Jude's violations led to a lead that injured him and had to be removed just two weeks after implantation. So long as Teixeira limits himself to proving that his Durata lead had a defect that resulted directly from FDA violations, his negligence claim is plausible and can proceed without concern for preemption. General negligence theories, though, leave room to allege a variety of duties that a defendant breached, and that is where the Court needs to make a minor adjustment. Teixeira's second claim, while including language about following federal law in parallel, also includes language that St. Jude had a duty to manufacturer that was "consistent with" federal requirements and that St. Jude "caused" Teixeira's lead to have improper and defective material and to be improperly designed. The Court needs to narrow that language to preclude any

possibility that a jury would be free to impose "consistent duties" and "causes" that differ from actual violations of FDA requirements.

To the extent that Teixeira's second claim leaves any room to allege duties beyond the FDA requirements in themselves, the Court recommends granting St. Jude's motion. The Court otherwise recommends denying St. Jude's motion.

E. *Failure to Warn (Negligence and Strict Liability)*

Next, the Court will assess Teixeira's third and fourth claims, which allege a failure to warn. The essence of these claims lie in nearly identical paragraphs in which Teixeira states that St. Jude "negligently failed to adequately warn doctors, the general public and Plaintiff of their lack of knowledge and/or knowledge of unsuitability such that Plaintiff, prior to implantation in 2011, would not have had the leads implanted in his body as alleged." (Dkt. No. 8 at 36–37, ¶¶ 147, 154.) To make these claims parallel to federal requirements, Teixeira submits a non-exhaustive list of provisions in Title 21 of the Code of Federal Regulations ("CFR") that allegedly defined the standard of care for providing warnings.

The problem with Teixeira's claims for failure to warn is that the respective federal and state requirements do not match as closely as Teixeira would like. The standard under New York law is somewhat expansive and relates directly to the public at large. "A manufacturer has a duty to warn against latent dangers resulting from foreseeable uses of its product of which it knew or should have known. A manufacturer also has a duty to warn of the danger of unintended uses

of a product provided these uses are reasonably foreseeable." *Liriano v. Hobart Corp.*, 700 N.E.2d 303, 305 (N.Y. 1998) (citations omitted). "A manufacturer is subject to liability where it has (1) reason to know that the product it markets is likely to be dangerous for the use for which it is supplied; (2) no reason to believe the user will realize its dangerous condition; and (3) fails to exercise reasonable care to inform the user of the facts which make the product dangerous." *Gonzalez by Gonzalez v. Morflo Indus., Inc.*, 931 F. Supp. 159, 167–68 (E.D.N.Y. 1996) (citations omitted). Under the New York standard, manufacturers have to communicate directly with users about intended uses and the associated dangers; they also have to brainstorm unintended but reasonably foreseeable uses and to communicate dangers for those uses as well. In contrast, Teixeira has not cited any federal regulations that impose a similarly broad duty on St. Jude. Under Title 21 of the CFR, St. Jude provides medical device reports to the FDA, and the FDA "*may* disclose to the public any report, including any FDA record of a telephone report, submitted under this part." 21 C.F.R. § 803.9(a) (emphasis added); *see also* 21 C.F.R. § 806.40(a) ("Any report submitted under this part is *available* for public disclosure in accordance with part 20 of this chapter.") (emphasis added). Sections 803.10, 803.50, and 803.52 impose no reporting requirements directly to users and require reporting only of information concerning actual malfunctions or injuries. Section 803.53(a) comes close with its reference to the need for "remedial action to prevent an unreasonable risk of

substantial harm to the public health," but that need first requires a reportable event. Section 814.80 concerns packaging and labeling but says nothing about intended and unintended uses. Other sections that Teixeira cites concern quality review.

The above differences between the federal standards that Teixeira cites and the New York standards for failure to warn mean that the two sets of standards are not parallel. The federal standards barely involve the public at all and create a close relationship between a manufacturer and the FDA with respect to quality review and reporting of adverse events that have occurred. *Cf. McConologue*, 8 F. Supp. 3d at 108 ("[Plaintiff] has failed to allege the existence of any FDA requirements applicable to consumer warnings such that the Court may determine whether a state failure to warn claim is different from, or in addition to FDA requirements and thus pre-empted, or contrastly whether the state duties parallel, rather than add to, federal requirements such that they are organic to or derivative of the device's premarket approval and thus not preempted.") (internal quotation marks and citation omitted); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 286–87 (E.D.N.Y. 2009) ("Plaintiff's failure to warn claim is thus an attack on the Trident System's federally approved label. Allowing the claim to proceed would permit a jury to find that defendants were required to provide warnings above and beyond those on the [Trident System's] product label—a label that was specifically approved by the FDA as part of the PMA

process.") (alteration in original) (internal quotation marks and citation omitted). The New York standards require manufacturers to maintain a close relationship with potential users about possible future events that are not obvious enough for them to realize on their own. *Cf. Becker v. Optical Radiation Corp.*, 66 F.3d 18, 20 (2d Cir. 1995) (affirming dismissal of claims including failure to warn, where "the common law of New York would impermissibly add requirements in the areas reviewed in the premarket approval process, and thus would impose standards on the [product] which are different from those of the MDA") (citations omitted). Under Section 360k(a) and *Riegel*, Teixeira cannot add New York's standards to St. Jude's responsibilities. The Court thus recommends dismissing Teixeira's third and fourth claims as preempted.

F. *Negligent Representation*

The Court now looks at Teixeira's fifth claim for negligent representation. A review of the New York standard will help determine whether this claim can parallel federal regulations governing the Durata lead. "It has long been the law in New York that a plaintiff in an action for negligent misrepresentation must show either privity of contract between the plaintiff and the defendant or a relationship so close as to approach that of privity." *Sykes v. RFD Third Ave. 1 Assocs., LLC*, 938 N.E.2d 325, 326 (N.Y. 2010) (internal quotation marks and citations omitted). "For there to be an actionable claim, the defendant must be under a duty to the plaintiff to exercise reasonable care in giving the information, and plaintiff's

reliance upon the information must be foreseeable. In elaborating on this test, we stated: There must be knowledge or its equivalent that the information is desired for a serious purpose; that he to whom it is given intends to rely and act upon it; that if false or erroneous he will because of it be injured in person or property. Finally the relationship of the parties, arising out of contract or otherwise, must be such that in morals and good conscience the one has the right to rely upon the other for information, and the other giving the information owes a duty to give it with care." *Heard v. City of N.Y.*, 623 N.E.2d 541, 545 (N.Y. 1993) (internal quotation marks and citations omitted).

Here, Teixeira faces two problems when trying to save his claim for negligent misrepresentation. Under Rule 12(b)(6) without even considering preemption, Teixeira has not alleged factually plausible privity between himself and St. Jude. The word "privity" does not appear at all in the claim. Teixeira has not alleged sufficient communication with St. Jude to that effect. Teixeira also has not alleged that St. Jude knew that he in particular would rely on specific information that it released. *Cf. Sykes*, 938 N.E.2d at 326 ("While [defendant] obviously knew in general that prospective purchasers of apartments would rely on the offering plan, there is no indication that it knew these plaintiffs would be among them, or indeed that [defendant] knew or had the means of knowing of plaintiffs' existence when it made the statements for which it is being sued."). Teixeira has alleged only that St. Jude had to provide the FDA with certain

information as part of the PMA process. From there, either the FDA would make the information available to the public, or St. Jude would broadcast the information generally without knowing which individuals might talk to their doctors about it. This information pathway does not suffice under New York law. Secondly, even if Teixeira's allegations survived scrutiny under Rule 12(b)(6), New York's requirement of privity does not match the relevant FDA regulations. As discussed above with the claims for failure to warn, the FDA does have extensive regulations requiring St. Jude to report product information to the agency before final approval. The regulations also require St. Jude to report adverse events to the agency, after they occur. From what Teixeira has pled and from what the Court can determine, nothing in the PMA process or other FDA regulations requires St. Jude to have a direct relationship with specific potential patients before those patients make a final decision to acquire a defibrillator. *Cf. Franzese v. St. Jude Med., Inc.*, No. 13-CV-3203 JS WDW, 2014 WL 2863087, at *8 (E.D.N.Y. June 23, 2014) ("The mere fact that Mr. Franzese purchased the Durata lead and defibrillator does not show that Mr. Franzese or his physicians actually relied on defendants' alleged misrepresentations and omissions when deciding whether to proceed with Mr. Franzese's surgery.") (editorial and internal quotation marks and citation omitted).

The absence of privity in the federal regulations means that they and the New York standard for negligent representation are not parallel. A jury could find

St. Jude liable for negligent representation only by finding that St. Jude breached a duty to provide accurate information directly to Teixeira, whose reliance on the information would be reasonably foreseeable. Such a jury finding would imply that privity existed between Teixeira and St. Jude. The findings of privity, foreseeability, and breach of duty all would constitute additions to the federal regulations. Section 360k(a) and *Riegel* forbid making those additions. The Court thus recommends dismissing Teixeira's fifth claim as both legally insufficient under Rule 12(b)(6) and preempted.

G. *Breach of Warranties*

Finally, the Court will assess Teixeira's sixth claim for breach of express and implied warranties. As mentioned above, Teixeira alleges two types of conduct by St. Jude that created express and implied warranties. The first type of conduct consists of the packaging materials for the defibrillator, through which St. Jude allegedly asserted that the defibrillator was safe and reasonably fit for its foreseeable and intended uses for which it was designed, manufactured, and assembled. The second type of conduct is more personal in nature. Teixeira alleges that St. Jude "made personal representations to Plaintiff and/or his treating medical providers that the devices utilized on Plaintiff were safe, long-lasting, and would not prematurely erode." (Dkt. No. 8 at 39 ¶ 173.) Teixeira alleges also that "[u]pon information and belief, Representatives of Defendants

made personal representations to Plaintiff and/or his treating medical providers that the devices utilized on Plaintiff would not require a surgical intervention." (*Id.* at 40 ¶ 174.)

As with Teixeira's other claims, a look at New York's standard for breach of warranties will provide some guidance. With respect to express warranties, plaintiffs need to define the warranties that defendants allegedly made and breached. *See, e.g., Davis v. N.Y.C. Hous. Auth.*, 668 N.Y.S.2d 391, 393 (N.Y. App. Div. 1998) ("The cause of action and the cross claim sounding in breach of express warranty, however, were properly dismissed, since the plaintiffs failed to set forth the terms of the warranty upon which they relied.") (citation omitted). Express warranties in recent years have more of a grounding in contract law than tort law. "The critical question is not whether the buyer believed in the truth of the warranted information . . . , but whether it believed it was purchasing the seller's promise as to its truth. This view of 'reliance'—i.e., as requiring no more than reliance on the express warranty as being a part of the bargain between the parties—reflects the prevailing perception of an action for breach of express warranty as one that is no longer grounded in tort, but essentially in contract. The express warranty is as much a part of the contract as any other term. Once the express warranty is shown to have been relied on as part of the contract, the right to be indemnified in damages for its breach does not depend on proof that the buyer thereafter believed that the assurances of fact made in the warranty would

be fulfilled. The right to indemnification depends only on establishing that the warranty was breached." *CBS Inc. v. Ziff-Davis Pub. Co.*, 553 N.E.2d 997, 1000–01 (N.Y. 1990) (editorial and internal quotation marks and citations omitted). While contractual in nature, express warranties do not always require a direct contract. "It may once have been true that the warranty which really induced the sale was normally an actual term of the contract of sale. Today, however, the significant warranty, the one which effectively induces the purchase, is frequently that given by the manufacturer through mass advertising and labeling to ultimate business users or to consumers with whom he has no direct contractual relationship. The world of merchandising is, in brief, no longer a world of direct contract; it is, rather, a world of advertising and, when representations expressed and disseminated in the mass communications media and on labels (attached to the goods themselves) prove false and the user or consumer is damaged by reason of his reliance on those representations, it is difficult to justify the manufacturer's denial of liability on the sole ground of the absence of technical privity." *Randy Knitwear, Inc. v. Am. Cyanamid Co.*, 181 N.E.2d 399, 402 (N.Y. 1962).

Breaches of implied warranties also concern buyer disappointment, but the assessment of the buyer's disappointment includes an assessment of the product's performance, not just the express promises that the seller made. "While the strict products concept of a product that is 'not reasonably safe'

requires a weighing of the product's dangers against its over-all advantages, the UCC's concept of a 'defective' product requires an inquiry only into whether the product in question was fit for the ordinary purposes for which such goods are used. The latter inquiry focuses on the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manners. The cause of action is one involving true 'strict' liability, since recovery may be had upon a showing that the product was not minimally safe for its expected purpose—without regard to the feasibility of alternative designs or the manufacturer's 'reasonableness' in marketing it in that unsafe condition. This distinction between the 'defect' analysis in breach of implied warranty actions and the 'defect' analysis in strict products liability actions is explained by the differing etiology and doctrinal underpinnings of the two distinct theories. The former class of actions originates in contract law, which directs its attention to the purchaser's disappointed expectations; the latter originates in tort law, which traditionally has concerned itself with social policy and risk allocation by means other than those dictated by the marketplace." *Denny v. Ford Motor Co.*, 662 N.E.2d 730, 736 (N.Y. 1995) (citation omitted).

The inclusion of design assessment in both Teixeira's allegations and in the standard for breach of implied warranty requires narrowing the claim for breach of implied warranty to keep it parallel with federal law. As noted above and in the parties' papers, the FDA requires device manufacturers to expend

great effort to bring a product all the way through the PMA process. The PMA process includes regulations about product design and what the manufacturing process for a Class III device should be. A state jury cannot be allowed to assess product fitness in any way that would add design and manufacturing requirements or that would otherwise second-guess the FDA regulatory scheme. Teixeira's claim for breach of implied warranty is preempted to the extent that it leaves room for second-guessing. That said, though, Teixeira has pled plausibly that St. Jude deviated from the specific manufacturing standards and procedures that the FDA prescribed for the defibrillator, and that the deviations in themselves created a defective product that injured him. The Court allowed the negligence and strict-liability causes of action to survive on that basis. There is no reason why the implied-warranty claim cannot survive on the same basis. *Cf. McConologue*, 8 F. Supp. 3d at 113–14 ("Indeed, courts have held that, where a plaintiff has pled a defective manufacturing claim, a state law claim for breach of implied warranty of merchantability is not preempted. Several courts that have addressed whether implied warranty claims are preempted after *Riegel* have determined that, to the extent the plaintiff relies on the failure to comply with the FDA's requirements in asserting his breach of implied warranty claim, such claims may proceed.") (citation omitted). So long as an eventual jury in this case receives instructions that only a deviation from FDA standards can equate to a lack of fitness for intended purposes, a finding of liability and an award of

damages would not add anything to St. Jude's federal responsibilities. Subject to this limitation, the Court recommends denying St. Jude's motion with respect to a claim for breach of implied warranty.

Returning to the claim for breach of express warranty, that claim also survives in part in a similar way. Teixeira asserts that one express warranty came from the defibrillator's packaging and its failure to indicate, *inter alia*, susceptibility to premature deterioration and violation of CGMP requirements. Teixeira has not pled what federal regulations would require those types of disclosures in product packaging, and the Court cannot allow a jury to add product packaging requirements to the requirements that the FDA already has established. *Cf. Desabio v. Howmedica Osteonics Corp.*, 817 F. Supp. 2d 197, 206 (W.D.N.Y. 2011) (Skretny, *C.J.*) ("[A] finding that a defendant violated state law by not living up to FDA-approved promises would necessarily conflict with the FDA's determination that the label was not false or misleading.") (citation omitted). Any of Teixeira's allegations concerning product packaging thus are preempted. Teixeira, though, also has alleged that St. Jude made direct, personal representations to him and his physicians that the defibrillator was safe, long-lasting, not subject to premature erosion, and not subject to subsequent surgical intervention. The Court is not aware of any federal regulations that required St. Jude to make those kinds of representations directly to Teixeira. If St. Jude stepped outside of the FDA requirements and volunteered to make

express, personal representations to Teixeira and his doctors then St. Jude should not be allowed to hide behind a regulatory scheme that has nothing to with that voluntary conduct. As for Rule 12(b)(6), Teixeira will have to confirm through discovery what representations St. Jude explicitly made, but for now, explicit personal representations from a manufacturer eager to sell a device plausibly could have happened. For these reasons, the Court recommends granting St. Jude's motion with respect to express warranty claims based on packaging and denying the motion with respect to express warranty claims based on explicit, personal representations.

IV. DISCUSSION—MOTION TO STRIKE

Finally, the Court turns to St. Jude's motion to strike. As noted above, St. Jude initially filed this motion as a motion to sanction Teixeira's counsel under Rule 11 or, alternatively, to strike portions of the amended complaint under Rule 12(f). St. Jude subsequently narrowed its motion to only the requests to strike, under Rule 11(b)(3) and Rule 12(f). The core of this motion is fairly straightforward. "St. Jude is simply requesting the Court to not accept as true, or to strike, these made up allegations that St. Jude violated non-existent PMA requirements related to the manufacture of Riata leads—which allegations Plaintiff has copied from another case to challenge the Durata lead at issue in this case." (Dkt. No. 24 at 2.) St. Jude asserts that the Riata and Durata leads for the defibrillator are different products approved separately by the FDA and containing

different materials. St. Jude asserts further that "there is no evidentiary basis for Plaintiff's allegation that his Durata lead suffered from the alleged product defect. Plaintiff neither includes nor attaches any medical report, device inspection or testimony from a physician or other expert. Plaintiff has no evidentiary support that his Durata lead suffered a Riata-like externalization lead failure." (*Id.* at 6.) St. Jude cites the case of *Pinsonneault v. St. Jude Med., Inc.*, No. 12-CV-1717 PJS/JSM, 2014 WL 2879754 (D. Minn. June 24, 2014), which granted summary judgment to St. Jude against a different plaintiff when that plaintiff could not cite evidence of federal requirements with respect to factors such as insulation thickness for defibrillator leads, placement of lumens, and crimp force. St. Jude concludes that "the fact that St. Jude waited until after receiving a summary judgment order in *Pinsonneault* to begin taking steps to stem the tide of parties copying the false allegations made up in *Pinsonneault* in no way means that the allegations have any merit or that St. Jude should be required to continually litigate groundless allegations devoid of any merit. Indeed, once on notice of the order in *Pinsonneault*, and having no independent basis for any reasonable, good faith belief in trying to force St. Jude to re-litigate the alleged existence of made-up PMA requirements, Plaintiff should have voluntarily withdrawn the Amended Complaint or the offending allegations." (*Id.* at 8–9.)

Teixeira opposes the motion in all respects. Teixeira asserts that the amended complaint resulted from extensive original research for both the Riata

and Durata defibrillator leads, and that the latter is simply a renamed "progeny" of the former. Teixeira denies being aware of *Pinsonneault* when drafting the amended complaint and denies copying any language from the complaint in that case. Teixeira concludes that "the Plaintiff in this case is not collaterally estopped by a finding in another case involving a different plaintiff, different lawyers, a different district court and what Defendants claim is a different product." (Dkt. No. 21 at 2.).

Resolving this motion requires revisiting some of the basic rules of pleading. "A pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." FRCP 8(a)(2). "'A short and plain statement of the claim' does not mean 'a short and plain statement of the eventual jury charge for that claim' or 'a short and plain recitation of the legal elements for that claim.' FRCP 8(a)(2) requires a plaintiff to state, in concise but plausible fashion, what he currently thinks a defendant actually did to him, subject to revision during later discovery." *Beswick v. Sun Pharm. Indus., Ltd.*, No. 10-CV-357A, 2011 WL 1585740, at *5 (W.D.N.Y. Mar. 4, 2011) (Arcara, *J.*). Just as plaintiffs need not submit evidence at the pleading stage, they also need not produce an exact list of legal authorities in play, because "under the Federal Rules of Civil Procedure, a complaint need not pin plaintiff's claim for relief to a precise legal theory." *Skinner v. Switzer*, 562 U.S.

521, 131 S. Ct. 1289, 1296 (2011). When necessary, plaintiffs can submit pleadings upon information and belief. "How else can a pleader avoid the appearance of perjury when he is without direct personal knowledge regarding one or more of the allegations necessary to his claim and therefore must plead on a less certain footing? Pleading on information and belief is a desirable and essential expedient when matters that are necessary to complete the statement of a claim are not within the knowledge of the plaintiff but he has sufficient data to justify interposing an allegation on the subject." Arthur R. Miller and Mary Kay Kane, 5 Fed. Prac. & Proc. Civ. § 1224 (3d ed. and 2014 Supp.). Only where pleadings will not find evidentiary support after a reasonable opportunity for further investigation should courts consider striking allegations as either frivolous or as impertinent and immaterial under Rules 11(b)(3) or 12(f). "Evidentiary questions, such as the one present in this case, should especially be avoided at such a preliminary stage of the proceedings. Usually the questions of relevancy and admissibility in general require the context of an ongoing and unfolding trial in which to be properly decided. And ordinarily neither a district court nor an appellate court should decide to strike a portion of the complaint on the grounds that the material could not possibly be relevant on the sterile field of the pleadings alone." *Lipsky v. Commonwealth United Corp.*, 551 F.2d 887, 893 (2d Cir. 1976) (citations omitted); *see also Anderson News, L.L.C. v. Am. Media, Inc.*, No. 09 CIV. 2227 PAC, 2013 WL 1746062, at *4 (S.D.N.Y. Apr. 23, 2013) ("A court

called upon to judge the reasonableness of an attorney's factual inquiry should consider how much time the attorney had for the investigation, the feasibility of verifying facts; the complexity of the factual issues; and the need for additional discovery to develop the factual claim.") (internal quotation marks and citation omitted).

Here, the allegations in the amended complaint reduce to a fairly simple story. Teixeira had a defibrillator and heart lead implanted in him on September 6, 2011. Just 14 days later, on September 20, 2011, Teixeira had to go back into surgery to have the lead removed. Presumably, Teixeira did not remove the lead himself; doctors would have diagnosed the need to do so. Why? For now, subject to discovery, Teixeira has chosen a particular theory to answer that question. Teixeira claims to have discovered that the Durata lead implanted in him was a modification of an existing product with a history of defects. Teixeira also claims to have found that the FDA flagged St. Jude in the past for violations of device requirements. From there, Teixeira pleads upon information and belief that the violations of known requirements and possibly others in themselves led to problems with the defibrillator lead that required his second surgery. Of course, Teixeira's medical records will play a major role in proving his allegations. Specifying every federal regulation in play would be helpful now and eventually will be necessary. Teixeira in general still has to expend great effort proving the connection between any federal violations and his injuries, though some of the

necessary information may be in St. Jude's exclusive control right now. The time for proof will come later, though. For now, what matters is that Teixeira has set forth a plausible story that a medical device with some red flags in its history had something to do with injuries that he suffered within 14 days of its implantation.

St. Jude's references to the *Pinsonneault* case merit a brief comment. St. Jude cites *Pinsonneault* as proof that Teixeira's allegations have no evidentiary basis. In that sense, St. Jude's request to strike amounts to an attempt at collateral estoppel. "There are two requirements for the application of collateral estoppel to an issue: (1) there must be an identity of issue which has necessarily been decided in the prior action and is decisive of the present action, and (2) there must have been a full and fair opportunity to contest the decision now said to be controlling." *Burgos v. Hopkins*, 14 F.3d 787, 792 (2d Cir. 1994). None of the criteria for collateral estoppel exist here. Teixeira was not a plaintiff in *Pinsonneault* and had no full and fair opportunity to litigate the issues in that case. The *Pinsonneault* decision came after pretrial discovery and the filing of a summary judgment motion. *Cf. Rosen v. St. Jude Med., Inc.*, No. 1:13-CV-1159 LEK/CFH, 2014 WL 4257863, at *15 n.10 (N.D.N.Y. Aug. 28, 2014) ("Moreover, the Court rejects Defendants' attempt to incorporate factual findings from *Pinsonneault v. St. Jude Medical, Inc.*, No. 12-cv-1717, 2014 WL 2879754, at *6 (D.Minn. June 24, 2014) to establish the absence of alleged PMA violations in this case. *Pinsonneault* concerned a motion for summary judgment, which

involves a different legal standard than a motion to dismiss, and is submitted after the parties have conducted discovery. *See Pinsonneault*, 2014 WL 2879754, at *3. Therefore, *Pinsonneault*'s factual findings are irrelevant to the instant Motion."). St. Jude is concerned that it defeated what, admittedly, do look like similar issues to Teixeira's case and now has to defend against them again. Without some sort of estoppel effect stretching from *Pinsonneault* to this case, however, Teixeira is entitled to explore his claims in pretrial discovery. The Court thus recommends denying St. Jude's motion to strike.

While recommending denial of the motion, the Court will send a note of caution to Teixeira. On the surface, some of the issues that arose in *Pinsonneault* do look like some of the issues that are emerging in this case. While *Pinsonneault* has no estoppel effect here, the existence of the *Pinsonneault* decision means that Teixeira now has notice of evidentiary issues that he will have to address. As just one example, Teixeira is now on notice that he will have to substantiate his claims that St. Jude violated federal requirements regarding insulation thickness for defibrillator leads, placement of lumens, and crimp force. If Teixeira cannot address the evidentiary issues for which he has notice and does not withdraw those assertions at some later time then he may have to compensate St. Jude for the cost of defending against those allegations. The Court's denial of the motion to strike, therefore, is without prejudice to future

motions that may be required to address allegations maintained despite pretrial discovery to the contrary.

V. CONCLUSION

For all of the foregoing reasons, the Court respectfully recommends granting St. Jude's motion to dismiss (Dkt. Nos. 4, 16) in part as follows:

1) Dismissing the second claim to the extent that Teixeira alleges duties beyond the FDA requirements in themselves;

2) Dismissing the third, fourth, and fifth claims in their entirety;

3) Dismissing the sixth claim for breach of implied warranty to the extent that Teixeira alleges anything other than a deviation from FDA standards that equates to a lack of fitness for intended purposes; and

4) Dismissing the sixth claim for breach of express warranty with respect to any allegations other than explicit, personal representations.

The Court recommends denying the motion in all other respects.

The Court also recommends denying St. Jude's motion to strike (Dkt. No. 18) without prejudice.

VI. OBJECTIONS

A copy of this Report and Recommendation will be sent to counsel for the parties by electronic filing on the date below. Any objections to this Report and

Recommendation must be electronically filed with the Clerk of the Court within 14 days. *See* 28 U.S.C. § 636(b)(1); FRCP 72. "As a rule, a party's failure to object to any purported error or omission in a magistrate judge's report waives further judicial review of the point." *Cephas v. Nash*, 328 F.3d 98, 107 (2d Cir. 2003) (citations omitted).

SO ORDERED.

/s Hugh B. Scott

HONORABLE HUGH B. SCOTT
UNITED STATES MAGISTRATE JUDGE

DATED: March 3, 2015